UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

JESSICA L. THORNTON,

Plaintiff,

-against-

BAYER HEALTHCARE PHARMACEUTICALS, INC.,

Defendant.

COMPLAINT

Case No.: 7:16-cv-239 (TJM/ATB)

Plaintiff, JESSICA THORNTON ("Plaintiff"), by and through her attorney, Bottar Leone, PLLC, as and for her complaint against BAYER HEALTHCARE PHARMACEUTICALS, INC., alleges as follows:

PARTIES

1. Plaintiff is a citizen of the State of New York and, at all relevant times, has resided at 752 County Route 24, Gouverneur, New York.

2. Upon information and belief, at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS INC. ("Defendant") was/is a corporation organized under the laws of the State of Delaware with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470.

3. Upon information and belief, at all relevant times, Defendant transacted and conducted business in the State of New York and derived substantial revenue from interstate commerce.

4. Upon information and belief, at all relevant times, Defendant expected or should have expected that its acts would have consequences within the United States of America, and the State of New York in particular, and derived substantial revenue from interstate commerce.

5. Upon information and belief, Defendant was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute MIRENA® as an intrauterine contraceptive system.

6. Upon information and belief, Defendant is the holder of the approved New Drug Application ("NDA") for the contraceptive device MIRENA®.

7. Upon information and belief, at all relevant times, Defendant includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

8. Upon information and belief, at all relevant times, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, MIRENA®.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal place of business in states other than the state in which the named Plaintiff resides.

10. Venue in this District is appropriate on the basis that plaintiff resides within the geographical boundaries of the United States District Court for the Northern District of New York and, more specifically, resides in Gouverneur, New York.

11. Plaintiff's case may be subject to transfer to the Mirena IUD Products Liability Litigation, 13-md-2434(CS) in the United States District Court for the Southern District of New York; however, Plaintiff does not waive any jurisdictional rights including, but not limited to, those recognized in *Lexecon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach*, 523 U.S. 26 (1998).

FACTUAL ALLEGATIONS

12. This is an action for damages suffered by Plaintiff, JESSICA THORNTON, who used the intrauterine device ("IUD") MIRENA® ("MIRENA®" or "the subject product").

13. Upon information and belief, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed MIRENA®.

14. Upon information and belief, when warning of safety and risks of MIRENA®, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration ("FDA"), to Plaintiff and the

public in general, that MIRENA® had been tested and was found to be safe and/or effective for its indicated use.

15. Upon information and belief, Defendant concealed its knowledge of MIRENA's® defects from Plaintiff, the FDA, the public in general and/or the medical community.

16. Upon information and belief, these representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, implant and/or purchase MIRENA® for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of Plaintiff.

17. Upon information and belief, Defendant negligently and improperly failed to perform sufficient tests, if any, on women using MIRENA® during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other contraceptives, which does not entirely and/or necessarily apply to the MIRENA® whatsoever.

18. Upon information and belief, Defendant was negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that Defendant was misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of MIRENA® and minimized the serious risks of the product.

19. Upon information and belief, as a result of the defective nature of MIRENA®, those persons who use and/or used and relied on MIRENA® have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

20. Plaintiff was injured due to her use of MIRENA®.

21. Upon information and belief, Defendant concealed its knowledge of the defects in its products from Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

22. Consequently, Plaintiff seeks compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper, as a result of her use of the MIRENA®, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk

pregnancies and infertility, lost wages, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

23. Upon information and belief, MIRENA® is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit.

24. Upon information and belief, the FDA approved Defendant's NDA for MIRENA® in December 2000.

25. Upon information and belief, today millions of women in the United States use MIRENA®.

26. Upon information and belief, MIRENA® has been used by more the 15 million women worldwide.

27. Upon information and belief, the MIRENA® system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control.

28. Upon information and belief, Defendant concedes that "[i]t is not known exactly how MIRENA® works," but provided that MIRENA® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

29. Upon information and belief, the MIRENA® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

30. Upon information and belief, the package labeling recommends that MIRENA® be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after MIRENA® use.

31. Upon information and belief, MIRENA®'s label does not warn about spontaneous migration of the IUD, but only states that migration may occur if the uterus is perforated during insertion.

32. Upon information and belief, Defendant has failed to alter its product packaging to reflect the growing number of MedWatch Adverse Event reports related to embedment of and perforation through the uterine lining and/or migration of the IUD through the uterine lining after the period of insertion.

33. Upon information and belief, Defendant has a history of overstating the efficacy of MIRENA® while understating the potential safety concerns.

34. Upon information and belief, in or around March 2009, the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) issued a warning regarding Defendant's advertising materials for MIRENA® that constituted misbranding of the IUD in violation of the Federal Food, Drug and Cosmetic Act and FDA's implementing regulations.

35. Upon information and belief, DDMAC pointed out that Defendant failed to communicate any risk information, inadequately communicated MIRENA®'s indications, and overstated the efficacy associated with the use of MIRENA® in Defendant-sponsored internet search engines.

36. Upon information and belief, DDMAC requested that Defendant immediately cease the dissemination of the violative materials.

37. Upon information and belief, in or around December 2009, Defendant was again contacted by DDMAC regarding a consumer-directed program entitled "MIRENA® Simple Style Statements Program," ("Simple Style Program") a live presentation designed for "busy moms." The Simple Style Program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

38. Upon information and belief, this Simple Style Program represented that MIRENA® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined that these claims were unsubstantiated and, in fact, pointed out that MIRENA®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

39. Upon information and belief, the Simple Style Program script also intimated that MIRENA® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that MIRENA® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

40. Upon information and belief, the portion of the Simple Style Program script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on MIRENA®.

41. Upon information and belief, Defendant falsely claimed that its system required no compliance with a monthly routine in contradiction of patient instructions.

42. Upon information and belief, and as a result of Defendant's violation of the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations, and Defendant was ordered to cease use of the violative materials.

PLAINTIFF SPECIFIC FACTUAL ALLEGATIONS

43. Plaintiff is 29 years old.

44. On or about February 27, 2013, Plaintiff received the MIRENA® IUD. Plaintiff tolerated the procedure well and neither Plaintiff nor her medical provider had any reason to suspect that the MIRENA® perforated her uterus.

45. On or about August 12, 2015, testing revealed that the Mirena® IUD was no longer in Plaintiff's uterine cavity.

46. Upon information and belief, shortly thereafter Plaintiff underwent a laparoscopic surgery to retrieve the Mirena® IUD which was embedded in Plaintiff's cul-de-sac in close association with her rectum.

47. As alleged herein, as a direct and proximate result of Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, Plaintiff suffered severe and permanent physical injuries, and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FEDERAL REQUIREMENTS

48. Defendant had an obligation to comply with the law in the manufacture, design and sale of MIRENA®.

49. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq.

50. Upon information and belief, Defendant failed to comply with federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements.

b. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from, or its quality or purity falls below, the standard set forth in the official compendium for MIRENA® and such deviations are not plainly stated on the labels.

c. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading.

d. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. MIRENA® is misbranded pursuant to U.S.C.§ 352 because it is dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. MIRENA® does not contain adequate directions for use pursuant to 21 C.F.R. §201.5 because, among other reasons of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes or uses for which it is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in their oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application and/or (e) route or method of administration or application.

h. Defendant violated 21 C.F.R. § 201.56 because the labeling was not informative and accurate.

i. MIRENA® is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated and new information became available that caused the labeling to become inaccurate, false or misleading.

j. Defendant violated 21 C.F.R. § 201.57 by failing to provide information that is important to the safe and effective use of the device including the potential of MIRENA® to migrate through the uterine lining or wall not related to insertion and the need for regular and/or consistent monitoring to ensure that the device has not migrated.

k. Defendant violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who used MIRENA®.

l. MIRENA® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it and steps that should be taken if they occur.

m. MIRENA® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the contraceptive device.

n. Defendant violated 21 C.F.R. § 201.57 because the possibility that the device could migrate through the uterine lining and/or wall not associated

with insertion is significantly more severe than the other reactions listed in the adverse reactions and yet Defendant failed to list the risk of migration before the other adverse reactions on the labeling of MIRENA®.

o. MIRENA® violates 21 C.F.R. § 210.1 because the process by which it was manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing or holding of a contraceptive device to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that it is purported or represented to possess.

p. MIRENA® violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

q. MIRENA® violates 21 C.F.R. § 211.165 because the test methods employed by Defendant are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity and/or reproducibility of test methods have not been properly established and documented.

r. MIRENA® violates 21 C.F.R. § 211.165 in that it fails to meet established standards or specifications and any other relevant quality control criteria.

s. MIRENA® violates 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints were not followed.

t. MIRENA® violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

u. Defendant violated 21 C.F.R. § 310.303 because they failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

v. Defendant violated 21 C.F.R. §310.305 and § 314.80 by failing to report adverse events associated with MIRENA® as soon as possible or at least within 15 days of the initial receipt by Defendant of the adverse event report.

w. Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to conduct an investigation of each adverse event associated with MIRENA® and failing to evaluate the cause of the adverse event.

x. Defendant violated 21 C.F.R. §310.305 and § 314.80 by failing to promptly investigate all serious, unexpected adverse experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

y. Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse experiences.

z. Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to properly identify the reports submitted such as by labeling them as "15-day Alert report" or "15-day Alert report follow-up."

aa. Defendant violated 21 C.F.R. § 312.32 because it failed to review all information relevant to the safety of MIRENA® or otherwise received by Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers as well as reports from foreign regulatory authorities that have not already been reported to the agency by the sponsor.

bb. Defendant violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse experience not already reported under the post-marketing 15-day alert report, and/or (c) a history of actions taken since the last report because of adverse experiences (for example, labeling changes or studies initiated).

cc. Defendant violated 21 C.F.R. § 314.80 by failing to submit a copy of a published article from scientific or medical journals along with one or more 15- day alert reports based on information from the scientific literature.

51. Upon information and belief, Defendant failed to meet the standard of care set by the above statutes and regulations which were intended for the benefit of individual consumers such as Plaintiff, making Defendant liable.

FIRST CAUSE OF ACTION AS AGAINST DEFENDANT
(NEGLIGENCE)

52. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

53. Upon information and belief, Defendant had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of MIRENA® into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

54. Upon information and belief, Defendant failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of MIRENA® into interstate commerce in that Defendant knew or should have known that using MIRENA® created a high risk of unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, lost wages, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

55. Upon information and belief, the negligence of Defendant, its agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not MIRENA® was safe for use; in that Defendant herein knew or should have known that MIRENA® was unsafe and unfit for use by reason of the dangers to its users;

d. Selling MIRENA® without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of MIRENA®;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, MIRENA®;

g. Failing to test MIRENA® and/or failing to adequately, sufficiently and properly test MIRENA®.

h. Negligently advertising and recommending the use of MIRENA® without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that MIRENA® was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that MIRENA® had the equivalent safety and efficacy as other forms of birth control/contraception;

k. Negligently designing MIRENA® in a manner which was dangerous to its users;

l. Negligently manufacturing MIRENA® in a manner which was dangerous to its users;

m. Negligently producing MIRENA® in a manner which was dangerous to its users;

n. Negligently assembling MIRENA® in a manner which was dangerous to its users;

o. Concealing information concerning FDA warnings from Plaintiff in knowing that MIRENA® was unsafe, dangerous, and/or non-conforming with FDA regulations; and

p. Improperly concealing and/or misrepresenting information from Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of MIRENA® compared to other forms of contraception.

56. Upon information and belief, Defendant under-reported, underestimated and downplayed the serious dangers of MIRENA®.

57. Upon information and belief, Defendant negligently compared the safety risk and/or dangers of MIRENA® with other forms of contraception.

58. Upon information and belief, Defendant was negligent in designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of MIRENA® in that it:

a. Failed to use due care in designing and manufacturing MIRENA® so as to avoid the aforementioned risks to individuals when MIRENA® was used for contraceptive purposes;

b. Failed to accompany its product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of MIRENA®;

c. Failed to accompany its product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of MIRENA®;

d. Failed to accompany its product with accurate warnings regarding the risks of all possible adverse side effects concerning MIRENA®;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of MIRENA®;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of MIRENA®, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

h. Was otherwise careless and/or negligent

59. Upon information and belief, despite the fact that Defendant knew or should have known that the MIRENA® caused unreasonable dangerous side effects, Defendant continued and continues to market, manufacture, distribute and/or sell MIRENA®, to customers, including Plaintiff.

60. Upon information and belief, Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

61. Upon information and belief, Defendant's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

62. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and

infertility, lost wages, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

63. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff may in the future be required to obtain further medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN)

64. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

65. Upon information and belief, at all times herein mentioned, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or recently acquired Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed MIRENA® as hereinabove described that was used by Plaintiff.

66. Upon information and belief, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

67. Upon information and belief, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff herein.

68. Upon information and belief, MIRENA® is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

69. Upon information and belief, at all times material to this action, MIRENA® was expected to reach, and did reach, consumers in all States and Territories throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

70. Upon information and belief, at all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences;

b. When placed in the stream of commerce, MIRENA® was defective in design and formulation, making the use of MIRENA® more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with other contraceptive devices, medications and similar drugs on the market of the prevention of pregnancy;

c. The subject product's design defects existed before it left the control of Defendant;

d. MIRENA® was insufficiently tested;

e. MIRENA® caused harmful side effects that outweighed any potential utility; and

f. MIRENA® was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendant strictly liable to Plaintiff.

71. Upon information and belief, Plaintiff was prescribed and used the subject product for its intended purpose.

72. Upon information and belief, Defendant created a product unreasonably dangerous for its normal, intended use.

73. Upon information and belief, Defendant knew, or should have known, that at all times herein mentioned MIRENA® was in a defective condition, and was and is inherently dangerous and unsafe.

74. Upon information and belief, Defendant, with this knowledge, voluntarily designed MIRENA® in a dangerous condition for use by the public, and in particular Plaintiff.

75. Upon information and belief, at the time the subject product left the control of Defendant, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative

designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

76. Upon information and belief, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

77. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, lost wages, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

78. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)

79. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

80. Upon information and belief, at all times herein mentioned, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed MIRENA® as hereinabove described that was used by Plaintiff.

81. Upon information and belief, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

82. Upon information and belief, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

83. Upon information and belief, the contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant, reached its intended users in the same defective and unreasonably dangerous condition in which the Defendant's MIRENA® was manufactured.

84. Upon information and belief, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff

in particular, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

85. Upon information and belief, Plaintiff was prescribed and used the subject product for its intended purpose.

86. Upon information and belief, Plaintiff could not by the exercise of reasonable care, have discovered MIRENA®'s defects herein mentioned and perceived its danger.

87. Upon information and belief, at all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendant;

c. The subject product was not made in accordance with Defendant's specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of Defendant.

88. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, lost wages, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

89. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

FOURTH CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

90. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

91. Upon information and belief, the contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings and/or inadequate testing.

92. Upon information and belief, MIRENA® was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature

menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

93. Upon information and belief, Plaintiff was prescribed and used the subject product for its intended purpose.

94. Upon information and belief, Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

95. Upon information and belief, Defendant, as a manufacturer and/or distributor of the subject prescription product, is held to the level of knowledge of an expert in the field.

96. Upon information and belief, the warnings that were given by Defendant were not accurate, clear and/or were ambiguous.

97. Upon information and belief, the warnings that were given by Defendant failed to properly warn physicians of the increased risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

98. Upon information and belief, Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of Defendant.

99. Upon information and belief, Defendant had a continuing duty to warn the Plaintiff of the dangers associated with the subject product.

100. Upon information and belief, by reason of the foregoing, Defendant has become strictly liable in tort to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, MIRENA®.

101. Upon information and belief, Defendant's inadequate warnings of MIRENA® were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

102. Upon information and belief, the defects in Defendant's MIRENA® product were a substantial factor in causing Plaintiff's injuries.

103. Upon information and belief, had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

104. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, lost wages, as well as the need for lifelong medical treatment, monitoring

and/or medications, and fear of developing any of the above named health consequences.

105. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

FIFTH CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY –
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS)

106. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

107. Upon information and belief, Defendant made representations regarding the safety of MIRENA®.

108. Upon information and belief, the subject product supplied by Defendant was defective in that it did not conform to representations made by Defendant regarding the safety of the subject product.

109. Upon information and belief, Plaintiff and her healthcare providers justifiably relied upon all of Defendant's representations regarding MIRENA® when they used and prescribed MIRENA®, respectively.

110. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration,

embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, lost wages, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

111. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY –
DEFECT DUE TO FAILURE OF ADEQUATE TESTING)

112. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

113. Upon information and belief, Defendant repeatedly advised consumers and the medical community that MIRENA® contained the same safety profile as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

114. Upon information and belief, Defendant failed to adequately test the safety of MIRENA® versus other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

115. Upon information and belief, had the Defendant adequately tested the safety of MIRENA® versus other hormonal contraceptives, intrauterine devices and other forms of birth control therapy and disclosed those results to the medical community and the public, Plaintiff and her healthcare providers would not have undertaken birth control therapy with MIRENA®.

116. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences

117. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

SEVENTH CAUSE OF ACTION AS AGAINST DEFENDANT (BREACH OF EXPRESS WARRANTY)

118. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

119. Upon information and belief, Defendant expressly warranted that MIRENA® was safe and well accepted by users.

120. Upon information and belief, the contraceptive MIRENA® does not conform to these express representations because MIRENA® is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendant. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

121. Upon information and belief, Plaintiff did rely on the express warranties of Defendant herein.

122. Upon information and belief, members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendant for use of MIRENA® in recommending, prescribing, and/or implanting MIRENA®.

123. Upon information and belief, Defendant herein breached the aforesaid express warranties, as its product MIRENA® was defective.

124. Upon information and belief, Defendant expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that MIRENA® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

125. Upon information and belief, Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that MIRENA® was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendant.

126. Upon information and belief, as a result of the foregoing acts and/or omissions Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

127. Upon information and belief, by reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendant's MIRENA® IUD.

128. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

EIGHTH CAUSE OF ACTION AS AGAINST DEFENDANT
(BREACH OF IMPLIED WARRANTIES)

129. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

130. Upon information and belief, at all times herein mentioned, Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold MIRENA® for use in contraception.

131. Upon information and belief, at the time Defendant marketed, sold, and distributed MIRENA® for use by Plaintiff, Defendant knew of the use for which MIRENA® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

132. Upon information and belief, Defendant impliedly represented and warranted to the users of MIRENA® and their physicians, healthcare providers, and/or the FDA that MIRENA® was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

133. Upon information and belief, said representations and warranties aforementioned were false, misleading, and inaccurate in that MIRENA® was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

134. Upon information and belief, Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

135. Upon information and belief, Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether MIRENA® was of merchantable quality and safe and fit for its intended use.

136. Upon information and belief, the contraceptive MIRENA® was injected into the stream of commerce by Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

137. Upon information and belief, Defendant herein breached the aforesaid implied warranties, as its product MIRENA® was not fit for its intended purposes and uses.

138. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

139. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes

and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

NINTH CAUSE OF ACTION AS AGAINST DEFENDANT
(FRAUDULENT MISREPRESENTATION)

140. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

141. Upon information and belief, Defendant falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff, and/or the FDA, and the public in general, that said product, MIRENA®, had been tested and was found to be safe and/or effective for contraceptive purposes.

142. Upon information and belief, representations made by Defendant were, in fact, false.

143. Upon information and belief, when said representations were made by Defendant, Defendant knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

144. Upon information and belief, these representations were made by said Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, implant and/or purchase said product, MIRENA®, for use as a means of birth control, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

145. Upon information and belief, at the time the aforesaid representations were made by Defendant and, at the time Plaintiff used MIRENA®, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

146. Upon information and belief, in reliance upon said representations, Plaintiff was induced to and did use MIRENA®, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

147. Upon information and belief, Defendant knew and was aware or should have been aware that MIRENA® had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

148. Upon information and belief, Defendant knew or should have known that MIRENA® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

149. Upon information and belief, Defendant brought MIRENA® to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

150. Upon information and belief, as a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish,

including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

151. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

TENTH CAUSE OF ACTION AS AGAINST DEFENDANT
(FRAUDULENT CONCEALMENT)

152. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

153. Upon information and belief, at all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the safety of MIRENA® for its intended use.

154. Upon information and belief, at all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the efficacy and risks associated with the use of MIRENA®.

155. Upon information and belief, Defendant knew or was reckless in not knowing that its representations were false.

156. Upon information and belief, in representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

a. That MIRENA® was not as safe as other forms of contraception;

b. That the risks of adverse events with MIRENA® were higher than those with other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

c. That the risks of adverse events with MIRENA® were not adequately tested and/or known by Defendant;

d. That Defendant was aware of dangers in MIRENA®, in addition to and above and beyond those associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

e. That MIRENA® was defective, and that it caused dangerous side effects, including but not limited to perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, in a much more and significant rate than other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

f. That patients needed to be monitored more regularly than normal while using MIRENA®.

g. That MIRENA® was manufactured negligently;

h. That MIRENA® was manufactured defectively;

i. That MIRENA® was manufactured improperly;

j. That MIRENA® was designed negligently;

k. That MIRENA® was designed defectively; and

l. That MIRENA® was designed improperly.

157. Upon information and belief, Defendant was under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of MIRENA®, including but not limited to the heightened risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause and infertility.

158. Upon information and belief, Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used MIRENA®, including Plaintiff, in particular.

159. Upon information and belief, Defendant's concealment and omissions of material facts concerning, inter alia, the safety of MIRENA® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and their physicians, hospitals and healthcare providers into reliance, continued use of MIRENA®, and actions thereon, and to cause them to purchase, prescribe, and/or implant MIRENA® and/or use the product.

160. Upon information and belief, Defendant knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding MIRENA®, as set forth herein.

161. Upon information and belief, Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed, which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

162. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

163. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

ELEVENTH CAUSE OF ACTION AS AGAINST DEFENDANT
(NEGLIGENT MISREPRESENTATION)

164. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. Upon information and belief, Defendant had a duty to represent to the medical and healthcare community, and to Plaintiff, the FDA and the public in general that said product, MIRENA®, had been tested and found to be safe and effective for birth control.

166. Upon information and belief, the representations made by Defendant were, in fact, false.

167. Upon information and belief, Defendant failed to exercise ordinary care in the representation of MIRENA®, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce,

in that Defendant negligently misrepresented MIRENA®'s high risk of unreasonable, dangerous side effects.

168. Upon information and belief, Defendant breached its duty in representing MIRENA®'s serious side effects to the medical and healthcare community, to Plaintiff, the FDA, and the public in general.

169. Upon information and belief, as a result of the negligent misrepresentations of Defendant set forth hereinabove, said Defendant knew and was aware or should have known that MIRENA® had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, infertility as well as other severe and personal injuries which are permanent and lasting in nature.

170. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

TWELFTH CAUSE OF ACTION AS AGAINST DEFENDANT
(FRAUD AND DECEIT)

171. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

172. Upon information and belief, Defendant conducted research and used MIRENA® as part of the research.

173. Upon information and belief, as a result of Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that MIRENA® was safe and effective for use as a means of providing birth control.

174. Upon information and belief, as a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including Plaintiff.

175. Upon information and belief, Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Plaintiff, as well as their respective healthcare providers and/or the FDA.

176. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media, contained material representations of fact and/or omissions.

177. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that Defendant's product MIRENA® was safe and effective for use as a form of birth control.

178. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's product MIRENA® carried the same risks, hazards, and/or dangers as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

179. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's product MIRENA® was more effective in treating the symptoms of heavy menstrual bleeding, encouraging the use of MIRENA® in circumstances other than those in which the product has been approved, over- promising the benefits, and minimizing the risk associated with MIRENA®.

180. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that MIRENA® was not injurious to the health and/or safety of its intended users.

181. Upon information and belief, the information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that MIRENA® was as potentially injurious to the health and/or safety of its intended users as other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

182. Upon information and belief, these representations were all false and misleading.

183. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to Defendant, and results that demonstrated

that MIRENA® was not safe as a means of contraception and/or was not as safe as other means of contraception, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

184. Upon information and belief, Defendant intentionally made material representations to the FDA and the public, including the medical profession, and Plaintiff, regarding the safety of MIRENA®, specifically but not limited to MIRENA® not having dangerous and serious health and/or safety concerns.

185. Upon information and belief, Defendant intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiff, regarding the safety of MIRENA®, specifically but not limited to MIRENA® being as safe a means of birth control as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

186. Upon information and belief, that it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA, and/or Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or Plaintiff, to falsely ensure the quality and fitness for use of MIRENA® and induce the public, and/or Plaintiff to purchase, request, implant, prescribe, recommend, and/or continue to use MIRENA®.

187. Upon information and belief, Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that MIRENA® was fit and safe for use as birth control.

188. Upon information and belief, Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that MIRENA® was fit and safe for use as birth control and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

189. Upon information and belief, Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to Plaintiff that MIRENA® did not present serious health and/or safety risks.

190. Upon information and belief, Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to Plaintiff that MIRENA® did not present health and/or safety risks greater than other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

191. Upon information and belief, these representations and others made by Defendant were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

192. Upon information and belief, these representations and others, made by Defendant, were made with the intention of deceiving and defrauding Plaintiff, including their respective healthcare professionals and/or the FDA, and were made in order to induce Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused Plaintiff to purchase, use, rely on, request, implant, recommend, and/or prescribe MIRENA®.

193. Upon information and belief, Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of MIRENA® to the public at large, and Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

194. Upon information and belief, Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of MIRENA® by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of MIRENA®.

195. Upon information and belief, Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on MIRENA® and/or that her respective healthcare providers would implant, prescribe, and/or recommend the same.

196. Upon information and belief, Defendant, through its public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including Plaintiff, as well as her respective healthcare professionals, would rely upon the information being disseminated.

197. Upon information and belief, Defendant utilized direct to consumer adverting to market, promote, and/or advertise MIRENA®.

198. Upon information and belief, Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant's representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of birth control and were thereby induced to purchase, use and rely on Defendant's product MIRENA®.

199. Upon information and belief, at the time the representations were made, Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of MIRENA®.

200. Upon information and belief, Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant, nor could Plaintiff with reasonable diligence have discovered the true facts.

201. Upon information and belief, had Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of MIRENA®, Plaintiff would not have purchased, used and/or relied on Defendant's product MIRENA®.

202. Upon information and belief, Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on Plaintiff.

203. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

204. Upon information and belief, as a result of the foregoing acts and omissions Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

THIRTEENTH CAUSE OF ACTION AS AGAINST DEFENDANT
(VIOLATION OF GBL §§ 349 and 350)

205. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

206. Upon information and belief, Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

207. Upon information and belief, Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

208. Upon information and belief, Defendant's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of

the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

209. Upon information and belief, New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendant violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendant knew it was defective and dangerous, and by other acts alleged herein.

210. Upon information and belief, Defendant engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

211. Upon information and belief, as a direct and proximate result of Defendant's violations of GBL §§ 349 and 350, Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

212. Upon information and belief, as a direct and proximate result of Defendant's violations of GBL §§ 349 and 350 and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff has suffered damages, for which Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

FOURTEENTH CAUSE OF ACTION AS AGAINST DEFENDANT
(PUNITIVE DAMAGES)

213. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

214. Upon information and belief, at all times material hereto, Defendant knew or should have known that the subject product was inherently more dangerous than alternative methods of birth control.

215. Upon information and belief, at all times material hereto, Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

216. Upon information and belief, Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff herein, concerning the safety of the subject product.

217. Upon information and belief, at all times material hereto, Defendant knew and recklessly disregarded the fact that MIRENA® causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

218. Upon information and belief, notwithstanding the foregoing, Defendant continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of birth control.

219. Upon information and belief, Defendant knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by MIRENA®.

220. Upon information and belief, Defendant intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff herein, the potentially life threatening side effects of MIRENA® in order to ensure continued and increased sales.

221. Upon information and belief, Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the subject product against its benefits.

222. Upon information and belief, as a direct and proximate result of Defendant's conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future.

223. Upon information and belief, the aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish and deter Defendant from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on each of the above-referenced claims and Causes of Action and as follows:

- Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, and economic loss, together with interest and costs as provided by law;
- Awarding punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;
- Awarding Plaintiff reasonable attorneys' fees;
- Awarding Plaintiff the costs of these proceedings; and
- Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

- Plaintiff hereby demands trial by jury as to all issues.

DATED: February 26, 2016

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